EPA United States Environmental Protection Agency

IRIS Handbook

IOAA Briefing
October 29th, 2018

Office of Research and Development
ETA, JC

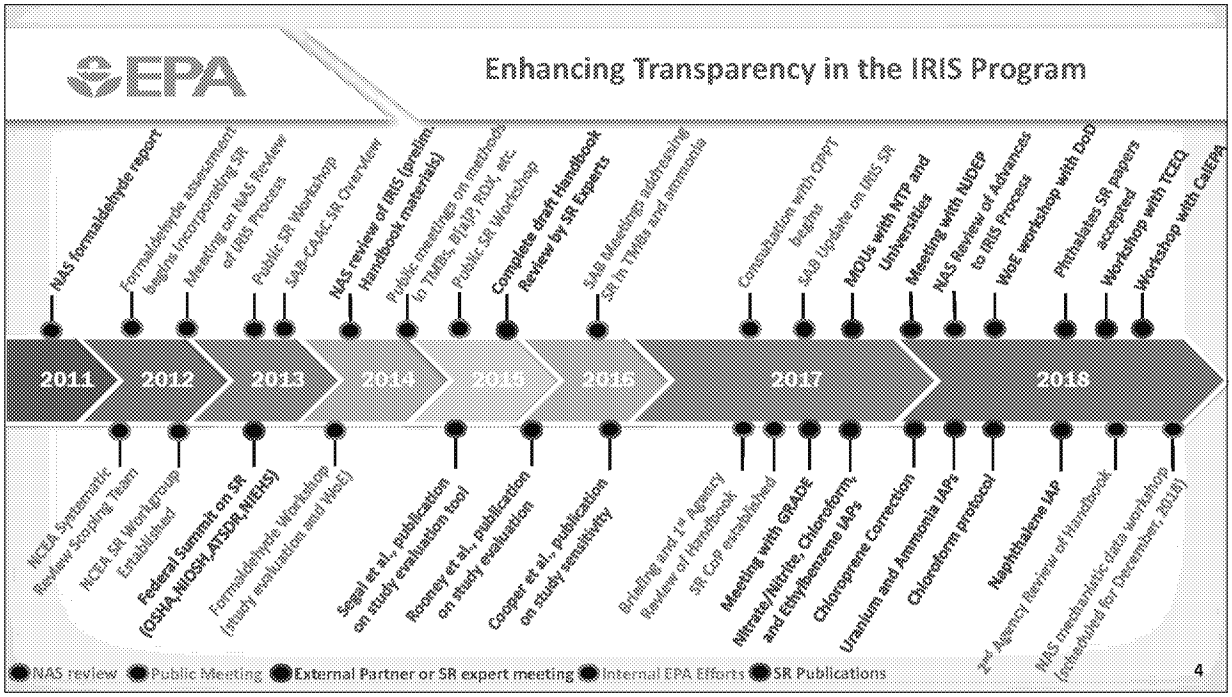
Why IRIS Developed the Handbook

- Need for standardized review practices across the IRIS Program, which is comprised of ~45 FTE across 4 NCEA Divisions in 3 locations (DC, RTP, Cincinnati).
- Direction in U.S. Congressional language
- National Academy of Sciences recommendations in 2011, 2014, and 2018
- Recommendations in multiple GAO reports to develop standardized methods and operating procedures. The most recent report (2017) cited top EPA leadership support of IRIS efforts to address these SAB and NAS recommendations as important.

Congressional Language

2018 Congressional Language (Consolidated Appropriations Act, FY18, #115-141)

"Finally, the Committees urge the expedited completion of the IRIS handbook and direct that the public be afforded an opportunity to provide comment on the handbook before it is placed in use."


EPA
Enhancing Transparency in the IRIS Program
NAS formaldehyde report
Formaldehyde assessment begins incorporating SR
Meeting on NAS Review of IRIS process
Public SR Workshop
SAB-CAAC SR Overview
NAS review of IRIS (preliminary Handbook materials)
Public meetings on methods to TMEs, BMAP, ROM, etc.
Public SR Workshop
Complete draft Handbook
Review by SR Experts
SAB Meetings addressing SR in TMEs and ammonia
Consultation with OPPT begins
SAB Update on IRIS SR
MOUs with NTP and Universities
Meeting with NJDEP
NAS Review of Advances to IRIS Process
WoE workshop with DoD
Phthalates SR papers accepted
Workshop with TCEQ
Workshop with CalEPA
2011
2012
2013
2014
2015
2016
2017
2018
NCEA Systematic Review Scoping Team
NCEA SR Workgroup Established
Federal Summit on SR (OSHA,NIOSH,ATSDR,NIEHS)
Formaldehyde Workshop (study evaluations and MoE)
Segal et al., publication on study evaluation tool
Rooney et al., publication on study evaluation
Cooper et al., publication on study sensitivity
Briefing and 1st Agency Review of Handbook
SR CoP established
Meeting with GRADE
Nitrate/Nitrite, Chloroform, and Ethylbenzene IAPs
Chloroprene Correction
Uranium and Ammonia IAPs
Chloroform protocol
Naphthalene IAP
2nd Agency Review of Handbook
IRIS mechanistic data workshop (scheduled for December, 2018)
NAS review
Public Meeting
External Partner or SR expert meeting
Internal EPA Efforts
SR Publications
4

Deliberative Process / Ex. 5

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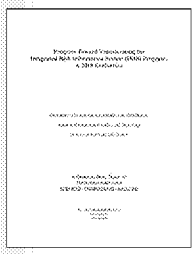
"The changes in the IRIS program over such a short period of time are impressive" –Dr. Jonathan Samet



The IRIS program has fully established systematic review in assessment development. The NAS 2018 review found that IRIS has :

- Instituted management structures to insure a high-quality process
- Provided early opportunities for external stakeholder input via release of assessment plans and protocols
- Established protocols that explicitly document methods
- Adopted computer applications with tools to promote efficiencies
- Supported research on systematic review methods and quantitative methods for toxicity values derivation

"The present committee urges that high priority be given to its [the Handbook] completion, peer review, and release."

Recent SAB-CAAC Reports

2015 (EPA-SAB-15-013):

"The SAB notes that *the process of systematic review still needs development*. Documentation of the process of identifying literature has progressed, but further development is needed in establishing standard practices for abstracting relevant data, for evaluating study quality, strengths and shortcomings, and for integration of evidence across studies."

- **Handbook Chapters 6, 8, and 11 address this specific recommendation**

2016 (EPA-SAB-16-003):

"*The SAB appreciates that the EPA is developing a handbook for the IRIS program* which will outline the tools and processes to address study quality and risk of bias...The EPA should provide sufficiently detailed criteria for each step of the process leading to the selection of key studies for the point of departure (POD) assessment while the handbook which will outline the tools and processes is being developed."

- **The Handbook describes how to transparently consider and document these decision steps, primarily in Chapters 4, 5, 6, and 12**

2017 (EPA-SAB-17-008):

"The SAB has observed significant enhancements in the IRIS program over the past few years, with impactful changes over the past year, and marked progress over the past six months. *The changes are so extensive and positive that they constitute a virtual reinvention of IRIS*"

"*The program has fully adopted the principles of systematic review*, and incorporated automation and publicly available software platforms to modernize the process. IRIS documents are now more modular and structured to enhance transparency and readability."

- **The SR processes described in the Handbook were shared with the public during a Sept. 27-28, 2017 SAB-CAAC meeting**

Peer Review Report for PFBS (2018)

"The process used was described well and was a very thorough and transparent approach to systematically evaluate each of the available scientific studies that described the health effects of PFBS"

"The overall framework for judging the health effect was systematic, objective, and unbiased."

"The toxicity assessment does an admirable job of synthesizing the available data on PFBS' effects … It is skillfully written and its liberal use of tables makes a substantial contribution to its organizational clarity. … The criteria for making a judgment as to whether the evidence supports a hazard are clearly described, while Table 7 summarizes the application of these criteria to each study and allows for a transparent process. In my opinion, the most challenging part of the toxicity assessment process is Evidence Integration and Hazard Characterization. In the case of PFBS, the challenge was more than met."

Deliberative Process / Ex. 5

NCEA is planning two FY19 NAS Workshops

1. Approaches to address mechanistic information in systematic reviews

- **Date:** December 10-11, 2018
- **Objective:** Explore relevant strategies and tools to inform methods development for the appropriate and pragmatic incorporation of mechanistic data in systematic reviews supporting EPA chemical assessments and prioritization efforts. Input received will help to address transparency in the context of evolving science.

2. Considerations for evidence integration and communicating human health effect conclusions

- **Date:** March 28-29, 2019
- **Objective:** Explore strategies that address challenges in evidence integration, or weight-of-evidence analysis, focusing on effectively communicating the degree of certainty in the available human, animal, and mechanistic evidence.

Deliberative Process / Ex. 5

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